SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Zolgensma® (onasemnogene abeparvovec-xioi) **IV (Medical) (J3399)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

☐ Standard reviews. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

A. Quantity Limit (max daily dose) [NDC Unit]:

- 1 kit (based on weight chart below)
- J3399 – Injection, onasemnogene abeparvovec-xioi, per treatment, up to $5x10^{15}$ vector genomes

B. B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 kit (based on weight chart below)
- 1 billable unit = 1 treatment, up to $5x10^{15}$ vector genomes

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Recommended Dosing: The recommended dose of Zolgensma® for single-dose intravenous infusion is 1.1 x 10^{14} vector genomes (vg)/kg based on the current patient weight in kg (within the last 14 days). Zolgensma® is provided as a customized kit to meet dosing requirements for each patient per their documented weight (in kilograms). Refer to the appropriate NDC number below for approval.

Patient Weight Range (kg)	Dose Volume (mL)*	Zolgensma Kit Configuration			NDC
		5.5 mL vial	8.3 mL vial	Total vials per kit	
2.6 to 3.0	16.5	0	2	2	71894-120-02
3.1 to 3.5	19.3	2	1	3	71894-121-03
3.6 to 4.0	22.0	1	2	3	71894-122-03
4.1 to 4.5	24.8	0	3	3	71894-123-03
4.6 to 5.0	27.5	2	2	4	71894-124-04
5.1. to 5.5	30.3	1	3	4	71894-125-04
5.6 to 6.0	33.0	0	4	4	71894-126-04
6.1 to 6.5	35.8	2	3	5	71894-127-05
6.6 to 7.0	38.5	1	4	5	71894-128-05
7.1 to 7.5	41.3	0	5	5	71894-129-05
7.6 to 8.0	44.0	2	4	6	71894-130-06
8.1 to 8.5	46.8	1	5	6	71894-131-06
8.6 to 9.0	49.5	0	6	6	71894-132-06
9.1 to 9.5	52.3	2	5	7	71894-133-07
9.6 to 10.0	55.0	1	6	7	71894-134-07
10.1 to 10.5	57.8	0	7	7	71894-135-07
10.6 to 11.0	60.5	2	6	8	71894-136-08
11.1 to 11.5	63.3	1	7	8	71894-137-08
11.6 to 12.0	66.0	0	8	8	71894-138-08
12.1 to 12.5	68.8	2	7	9	71894-139-09
12.6 to 13.0	71.5	1	8	9	71894-140-09
13.1 to 13.5	74.3	0	9	9	71894-141-09
13.6 to 14.0	77.0	2	8	10	71894-142-10
14.1 to 14.5	79.8	1	9	10	71894-143-10
14.6 to 15.0	82.5	0	10	10	71894-144-10
15.1 to 15.5	85.3	2	9	11	71894-145-11
15.6 to 16.0	88.0	1	10	11	71894-146-11
16.1 to 16.5	90.8	0	11	11	71894-147-11
16.6 to 17.0	93.5	2	10	12	71894-148-12
17.1 to 17.5	96.3	1	11	12	71894-149-12
17.6 to 18.0	99.0	0	12	12	71894-150-12
18.1 to 18.5	101.8	2	11	13	71894-151-13
18.6 to 19.0	104.5	1	12	13	71894-152-13
19.1 to 19.5	107.3	0	13	13	71894-153-13
19.6 to 20.0	110.0	2	12	14	71894-154-14
20.1 to 20.5	112.8	1	13	14	71894-155-14
20.6 to 21.0	115.5	0	14	14	71894-156-14

*Dose volume is calculated using the upper limit of the patient weight range for pediatric patients less than 2 years of age between 2.6 kg and 21.0 kg

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Coverage will be provided for one treatment course and may NOT be renewed.

- ❑ Member is less than 2 years of age
- ❑ Medication is prescribed by a physician who has consulted with or who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders
- ❑ If the member is a premature neonate, full-term gestation age of 39 weeks and 0 days has been met [**NOTE**: Full-term gestational age can be defined as the postmenstrual age (gestational age plus chronological age) being equal to ≥ 39 weeks and 0 days]
- ❑ Prescriber must submit baseline documentation of **ONE** of the following [**NOTE**: Actual completed assessment with results provided must be submitted. Do not send the result number within progress notes]
  - ❑ Hammersmith Infant Neurological Exam (HINE) (infant to early childhood)
  - ❑ Hammersmith Functional Motor Scale Expanded (HFMSE)
  - ❑ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
- ❑ Member has had a genetic test confirming the diagnosis of spinal muscular atrophy with bi-allelic pathogenic variants in the survival motor neuron 1 (SMN1) gene **(submit documentation) [NOTE**: Pathogenic variants may include homozygous deletion, compound heterozygous mutation, or a variety of other rare mutation]
- ❑ Member meets **ONE** of the following **(submit documentation)**:
  - ❑ Member has < 3 copies of the survival motor neuron 2 (SMN2) gene
  - ❑ Member has an absence of the c.859G>C single base substitution modification in exon 7 of the survival motor neuron 2 (SMN2) gene
- ❑ According to the prescribing physician, member has started or will receive systemic corticosteroids equivalent to oral prednisolone at a dose of 1 mg/kg per day commencing 1 day prior to Zolgensma® infusion and for a total of 30 days
- ❑ Baseline anti-AAV9 antibody titers are ≤ 1:50 **(submit documentation)**
- ❑ Member has undergone a liver function assessment within the last 30 days and meets **ALL** the following **(submit documentation)**:
  - ❑ Alanine aminotransferase levels are ≤ 2 times the upper limit of normal
  - ❑ Aspartate aminotransferase levels are ≤ 2 times the upper limit of normal
  - ❑ Total bilirubin levels are ≤ 2 times the upper limit of normal [**NOTE**: Members with elevated bilirubin levels due to neonatal jaundice are acceptable]
  - ❑ Prothrombin time results are ≤ 2 times the upper limit of normal
- ❑ Member has undergone a renal function assessment within the last 30 days and has a creatinine level < 1.0 mg/dL **(submit documentation)**

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- ❑ A complete blood count has been obtained within the last 30 days and the member meets **BOTH** of the following **(submit documentation)**:
  - ❑ White blood cell count is ≤ 20,000 cells per mm^3
  - ❑ Hemoglobin levels are between 8 g/dL and 18 g/dL
- ❑ Member has **NOT** received Zolgensma® in the past **(verified by medical paid claims)** [**NOTE**: Verify through claims history that the member has not previously received Zolgensma®. If no claim for Zolgensma® is present, the prescribing physician confirms that the member has not previously received Zolgensma®]
- ❑ For members currently receiving or who has received prior treatment with Spinraza® (nusinersen intrathecal injection), the prescribing physician confirms that further therapy with Spinraza® will be discontinued
- ❑ For members currently receiving or who has received prior treatment with Evrysdi® (risdiplam oral solution), the prescribing physician confirms that further therapy with Evrysdi® will be discontinued

Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee:** 7/18/2019
REVISED/UPDATED: ~~9/25/2019; 12/4/2020; 10/21/2021,~~ **01/15/2025**